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January 31, 1979

Hearing Clerk  
Food and Drug Administration  
Room 4-65  
HFA-305  
5600 Fishers Lane  
Rockville, Maryland 20857

RE: DOCKET NO. 78N-0065

Gentlemen:

Enclosed herewith are comments, in quintuplicate, to be filed in response to the Federal Register Notice, dated November 3, 1978 relating to The Proposed Monograph for OTC Skin Bleaching Drug Products.

Very truly yours,

A handwritten signature in dark ink, appearing to read "Richard Serbin". The signature is written in a cursive, somewhat stylized script.

Richard Serbin  
Regulatory Counsel

RS/ng

78N-0065

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Re: Docket No. 78N-0065  
Federal Register Notice, November 3, 1978  
Proposed Monograph for OTC Skin Bleaching  
Drug Products (43 FR 51553 et. seq.)

Norcliff Thayer markets a line of hydroquinone containing products under the trade names ESOTERICA<sup>R</sup> and GOLDEN PEACOCK<sup>R</sup>. These products have been on the market for approximately thirty-five years.

We have reviewed the Federal Register Notice of November 3, 1978, (docket No. 78N-0065) and have the following statements to make concerning the proposed Labeling Section: 21 CFR 358.50 and the proposed Definition Section: 21 CFR 358.3.

I. PRODUCT LABELING

The labeling of these products as skin bleaching drug products is an inappropriate designation or categorization. Our research indicates that this would be very confusing to the Black segment of the market in that only 31% of all Black users of these products refer to them as Bleach creams. The research\* indicates the following terms being used by Blacks to describe a Hydroquinone product:

- Skin toners	49%
- Skin Creams	42%
- Skin Lighteners	40%
- Medicated Skin Creams	33%
- Bleaching Creams	31%
- Skin Treatments	37%

\*based on responses from 337 Black users

Thus our concern is over the potential confusion as to product action and benefits if the use of Bleach is required. For example, it might confuse some of the Black users into believing they should discontinue use of the product since it will cause their skin to turn white, rather than simply lighter.

In addition to possible confusion among Black consumers, the term bleaching is technically incorrect. While it is true that the end result (the lightening or removal of color) is the same as is accomplished by a bleaching agent, the mechanisms involved are entirely different. A chemical bleach such as Clorox, or the bleaching effect of sunlight, removes colors which are already present by altering the molecule of the color. Hydroquinone, on the other hand, does not remove an existing color (skin pigment) but partially blocks the body's ability to produce the pigment.

We propose the use of the following terminology: a product for lightening brownish skin discolorations.

## II. WARNING STATEMENTS

1. The first statement under warnings reads:

"Sun exposure should be avoided indefinitely by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin in order to prevent darkening from reoccurring."

"This warning should be conspicuously boxed in red letters."

COMMENT: We object to this statement for several reasons.

First, a warning statement should be used only to warn consumers of some harmful effect that might occur if they use a particular product. The above statement has nothing to do with a skin lightening product, but rather is a general educational statement only. The implication is that unless you continue to cover/protect the area lightened, it will darken again if it is exposed to the sunlight. This does not merit the use of such a powerful word as "warning" attached to it. There is no evidence that skin darkening is harmful. Although the incidence of skin cancer and premature aging of the skin is related to continued over exposure to sunlight, the proposed warning statement does not address either of these two factors.

Additionally, one of the conditions for which skin lightening products are recommended is melasma which some women develop during pregnancy or while taking oral contraceptives. Sunlight may increase the intensity of the pigmentation, but it can also occur without any direct exposure to sunlight. That is, it can occur during the winter months as well as during the summer. Thus, the proposed warning statement would have no meaning in this case.

To require the warning statement to be boxed and in red letters seems inappropriate.

2. The second proposed warning statement is:

"Avoid contact with eyes".

COMMENT: This should not be classified as a warning statement but rather as a caution.

3. The third warning statement is:

"If skin irritation develops, use of this product should be discontinued or a physician should be consulted."

COMMENT: Again, this is a caution, not a warning. 21 CFR 369.20 "Drug; recommended warnings and caution statements" contains many examples of labeling cautions presently in use for various OTC drug products meant for topical administration.

4. "If improvement is not seen after 2 months of treatment, use of this product should be discontinued."

COMMENT: This statement is neither a warning nor a caution. It is simply to inform the consumer that if the product does not do anything after using it for two months, there is no reason to continue using it. This statement should not be included in labeling for these products.

21 CFR 369.20 "Drug; recommended warnings and caution statements" contains many examples of labeling cautions presently in use for various OTC drug products meant for topical administration.

5. "Not recommended for use in children under 12 years of age".

COMMENT: This should not be treated as a warning or as a caution. It should be regarded similarly to statements such as:

"For external use only", or, "Keep out of reach of children".  
Further, we are not aware of any data which supports the inclusion of this statement in the labeling.

6. "Depigmentation (lightening) effect of this product  
may not be noticeable when used on very dark skin".

COMMENT: We know that dark skinned people use these products with satisfaction and to even skin tones. We are not aware of any data which supports the inclusion of this statement in the labeling.

7. "This product will bleach skin and is not for use  
for the prevention of sunburn".

COMMENT: Since no claim is made for the prevention of sunburn for these products, the inclusion of such a statement is unwarranted.

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